UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

In re Celgene Corporation Securities Litigation.	Case No. 18-cv-04772 (JMV) (JBC) CLASS ACTION ORAL ARGUMENT REQUESTED

REVISED MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

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Defendants Celgene Corporation, Mark Alles, Robert Hugin, Scott Smith, Peter Kellogg, Terrie Curran, Jacqualyn Fouse, Philippe Martin, Nadim Ahmed, Jonathan Tran, and Peter Callegari respectfully move to dismiss this action brought by Lead Plaintiff AMF Pensionsforsakring AB, asserting claims under (i) Section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder (the "Section 10(b) claim"), and (ii) Section 20(a) of the Exchange Act, 15 U.S.C. § 78n(a) (the "Section 20(a) claim").[1]

I. INTRODUCTION

Plaintiff's kitchen-sink, 200-page Amended Complaint (the "Complaint") is built around the notion that Celgene desperately needed to find a blockbuster replacement drug for its hugely successful cancer drug Revlimid, which the Complaint asserts will lose patent exclusivity in 2022.[2] From this, Plaintiff spins a story that Defendants "embarked on a campaign to fraudulently misrepresent" that three Celgene drugs—GED-0301, Otezla, and Ozanimod—"were poised to be billion-dollar blockbusters and provide massive revenues after Revlimid went off patent," which Defendants allegedly knew "was nowhere near the truth." Compl. ¶ 4. But

[1] Defendants dispute Plaintiff's allegations but accept the well-pleaded allegations as true for purposes of this motion. Defendants' motion rests on those allegations, documents referenced in the Complaint, and judicially noticeable materials, all of which may be properly considered on a motion to dismiss. *See, e.g.*, *In re Hertz Global Holdings Inc.*, 905 F.3d 106, 111 n.1 (3d Cir. 2018).

[2] Plaintiff seeks to represent a class of all individuals who purchased Celgene stock between January 12, 2015 and April 27, 2018 (the "Class Period").

Defendants' statements to investors about the prospects of these three drugs could not *actually* make them adequate replacements for Revlimid. Plaintiff's theory thus makes little sense. It is no wonder, then, that Plaintiff has failed to allege a securities fraud claim with respect to any of the drugs.

A. GED-0301

Plaintiff first contends that Defendants misrepresented the study results for GED-0301. Celgene acquired GED-0301 in 2015 for a record upfront payment of $710 million, but ultimately stopped the drug's clinical trials in 2017. Plaintiff claims that Defendants misled investors by positively characterizing the drug's Phase II and Phase Ib clinical trial data during that time, because those studies were purportedly flawed.

But the study designs and results, including the alleged flaws, were all publicly disclosed, which precludes liability as a matter of law for Defendants' characterizations of them. And, in any event, Defendants' statements about the data were classic puffery that is not actionable as securities fraud. Defendants' characterizations were also mere opinions, which cannot give rise to liability unless they are both not honestly believed *and* without a reasonable basis—and Plaintiff alleges neither requirement. Indeed, Celgene was far from alone in its positive view of GED-0301's Phase II and Phase Ib data.

Plaintiff also claims that Defendants made misleading statements about the timeline for GED-0301's regulatory approval, by publicly stating that the drug could

potentially be approved in 2019. But these statements are protected by the safe harbor for forward-looking statements in the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u-5, for two independent grounds. First, Defendants' statements were accompanied by a warning that the drug might never be approved. And second, the statements were not made with "actual knowledge" of their falsity. Indeed, Plaintiff's only basis for claiming otherwise is the speculative hearsay of two unidentified witnesses that certain unidentified persons at Celgene secretly (and implausibly) decided to "scrap" GED-0301 months before Celgene ended the costly Phase III trial—but such hearsay warrants little if any weight and, even if credited, is not a view that Defendants are alleged to have shared. Moreover, even without the PSLRA safe harbor, Defendants' statements about GED-0301's potential regulatory approval are not actionable because the statements are all opinions, with no plausible (much less particularized) allegation that the statements were not honestly believed or lacked a reasonable basis.

In addition, separate from the above arguments, Plaintiff has not adequately alleged scienter for any purported misstatements about GED-0301. Celgene's large investments in and forthright disclosures about the drug and its clinical trial data cannot be squared with knowing fraud about the drug's efficacy. In addition to speculative, anonymous hearsay that cannot carry Plaintiff's steep pleading burden, Plaintiff highlights purportedly suspicious stock sales by three of the individual Defendants and certain employee departures, but the case law makes clear that, as

alleged, neither of these suggests impropriety.

B. Otezla

With regard to Otezla, which the FDA approved in 2014, Plaintiff claims that Defendants misled investors for years about the drug's ability to meet sales projections for 2017. Plaintiff claims that the projections were never achievable and that Defendants' statements that Celgene could meet them—going back to 2015—were fraudulent.

But these statements are almost all forward-looking statements protected by the PSLRA safe harbor. They were accompanied by meaningful cautionary language, and Plaintiff does not allege that Defendants had actual knowledge (for years) that the projections would be not be met. Indeed, Oztela's history of strong sales—which grew every quarter from 2015 through 2016 and hit an all-time high in the second quarter of 2017—preclude any inference that Defendants were simultaneously lying to investors about the 2017 projections, as the Third Circuit has held. Plaintiff offers a smattering of confidential witnesses who allegedly doubted Celgene's ability to hit the Otezla projections, but none of these witnesses addresses Defendants' knowledge. Nor, in any event, do any of the witnesses offer a particularized claim that Otzela's total sales would fall short of the 2017 guidance.

Defendants' non-forward-looking statements about Otezla are also not actionable. These statements are largely puffery and, in any event, are not adequately alleged to have been false or misleading.

Plaintiff also has not adequately alleged scienter for any of Defendants' purported misstatements about Otezla. Given Otezla's robust performance through the second quarter of 2017, the natural—and far stronger—inference is that Defendants honestly and reasonably (or, at worst, negligently) believed the drug would continue to sell well and meet the 2017 projections.

C. Ozanimod

Finally, Plaintiff's Section 10(b) claim regarding Ozanimod arises out of the FDA's refusal to accept the New Drug Application ("NDA") for Ozanimod—instead issuing a Refusal-to-File ("RTF") letter—because Celgene had not conducted additional testing of one of Ozanimod's metabolites (chemical byproducts created when the body breaks down the drug). Plaintiff complains about Defendants' statements that Celgene intended to file the Ozanimod NDA by the end of 2017, that the drug's Phase III trials were ongoing, and that Celgene had indeed filed the NDA in December 2017. Although all of these statements were true, Plaintiff nonetheless contends they were misleading because Celgene did not disclose that it had not yet completed the metabolite testing.

But, contrary to Plaintiff's contention, it was not a foregone conclusion that the FDA would reject the Ozanimod NDA without the extra metabolite testing. Instead, Plaintiff's own allegations demonstrate that the metabolite testing was only recommended, not mandatory. Defendants' truthful statements were therefore not misleading at all.

Additionally, Defendants' statements about filing the NDA by the end of 2017 are also forward-looking statements protected by the PSLRA safe harbor. Not only were the statements accompanied by meaningful cautionary language, but Plaintiff fails to adequately allege that Defendants *knew* the NDA would be rejected (and yet still submitted it and discussed it publicly).

And, in any event, Plaintiff's scienter allegations similarly fall flat for this theory. Plaintiff does not allege any plausible reason why Defendants would mislead investors about the Ozanimod NDA if the FDA was guaranteed to quickly reject it. Moreover, Plaintiff's reliance on yet more anonymous hearsay is yet again insufficient.

II. PLAINTIFF'S SECTION 10(B) CLAIM REGARDING GED-0301 SHOULD BE DISMISSED.

A. Factual Background

1. Celgene Acquires the Rights to GED-0301.

In April 2014, Celgene paid $710 million to Nogra Pharma Ltd. ("Nogra") for the rights to develop and commercialize GED-0301 for the treatment of Crohn's disease and other indications. Compl. ¶¶ 108–09.[3] This was the "largest upfront payment any drug company had ever made to acquire a single drug." *Id.* ¶ 108. Celgene also agreed to pay Nogra nearly $2 billion more based on the achievement of various development, regulatory, and sales milestones for GED-0301. *Id.*

[3] Crohn's disease is an inflammatory bowel disease that afflicts millions of Americans but has limited treatments. Compl. ¶¶ 105–06. GED-0301's advantages over those treatments suggested it could be a lucrative entrant into a sizable market. *Id.* ¶ 107.

When Celgene acquired the rights to GED-0301, Nogra had already completed Phase I and Phase II trials of the drug. *Id.* ¶ 110–11.[4] In deciding to acquire the drug, Celgene relied heavily on the results from these studies. *Id.*

In the April 2014 press release announcing the deal with Nogra, Celgene disclosed that "[a] double-blind, placebo-controlled, multicenter phase II trial of three doses of GED-0301 in 166 patients with active Crohn's disease has been completed," and that the results "have been submitted to a major medical journal and will be presented at an upcoming medical congress." Ex. 2 (4/24/14 PR) at 1;[5] *see also* Compl. ¶ 111. The press release stated that "GED-0301 is a potentially transformative therapy that demonstrated striking clinical activity" in the Phase II trial and that, "[b]ased upon these results, Celgene plans to initiate a phase III registration program by year-end 2014." *Id.*

On a January 29, 2015 call to discuss its earnings for the previous quarter, Celgene reiterated that the results of the Phase II trial would be published "in a major

[4] To obtain regulatory approval for a new drug like GED-0301, "FDA regulations require three phases of clinical trials—which may overlap—to assess the [drug's] efficacy and safety." *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 163 n.5 (3d Cir. 2014) (citing 21 C.F.R. § 312.21). Phase I trials "test[] the drug's efficacy and safety on a small number of patients." *Id.* Phase II trials test varying dosages of the drug "on groups of up to several hundred patients to evaluate preliminary indicia of the drug's efficacy and safety." *Id.* And Phase III trials are "randomized, multicenter trials on large patient groups over an extended period [that] aim to provide sufficient evidence of efficacy and safety to support FDA approval to market the drug." *Id.*

[5] All exhibits cited herein are exhibits attached to the Declaration of Lawrence S. Lustberg filed contemporaneously herewith.

medical journal." Ex. 3 (01/29/15 Call Tr.) at 8; *see also* Compl. ¶¶ 111, 135. Celgene also announced that, "in staggered parallel fashion" with the Phase III trial, it would be conducting a "registration enabling endoscopy study," *id.* at 7—known as the "Phase Ib study"—that "would be designed to show both clinical remission and objective endoscopic evidence of efficacy," Compl. ¶ 136.

2. Celgene Announces the Results of Nogra's Phase II Study, Which Is Widely Noted to Lack an Endoscopic Endpoint.

On March 18, 2015, Celgene issued a press release announcing that the results of Nogra's Phase II study on GED-0301 had been published in the New England Journal of Medicine ("NEJM"). Compl. ¶ 137. The press release also disclosed that the study's primary outcomes, or endpoints, rested on Crohn's Disease Activity Index (CDAI) scores, and not on endoscopic confirmation of the reduction in disease. *See* Ex. 4 (3/18/15 PR).[6] Celgene's press release further stated that "[w]e are encouraged by the phase II data and are committed to bringing innovative medicine to patients with Crohn's disease, starting with advancing the phase III trial for GED-0301." *Id.* at 1.

The Phase II study design and results were discussed in even greater detail in

[6] The CDAI measures symptom severity as reported by patients but does not include endoscopic assessment. Compl. ¶ 119. Endoscopies—which are intestinal examinations using a flexible camera—can provide evidence of mucosal healing, which, by 2015, had become an increasingly important endpoint for the regulatory approval of Crohn's disease treatments. *Id.* ¶¶ 119 n.5, 120.

the NEJM.[7] Like Celgene's March 2015 press release, the NEJM article made clear that the study relied on CDAI scores and did not include an endoscopic endpoint. *See* Ex. 5 (Monteleone Art.). Indeed, the article noted that "[i]deally further clinical study of [GED-0301] for Crohn's disease should . . . assess mucosal healing on the basis of endoscopic analyses." *Id.* at 1111. Still, based on the Phase II results, the authors of the NEJM article concluded that "study participants with Crohn's disease who received [GED-0301] had significantly higher rates of remission and clinical response than those who received placebo." *Id.* at 1104.

In an editorial that accompanied the NEJM article, Dr. Severine Vermeire described GED-0301's Phase II data as "impressive" and "unprecedented," and noted that the drug could "represent a first step toward curing [Crohn's] disease." Ex. 6 (Vermeire Art.). But Dr. Vermeire also noted that the Phase II study was "based on CDAI score" without "more objective criteria for active disease," and that the lack of "[e]ndoscopic confirmation" made it "unclear what proportion of patients underwent randomization without actually having mucosal lesions." *Id.* at 1166–67. While acknowledging that CDAI scores were an endpoint "recommended by regulatory bodies," Dr. Vermeire observed "a lack of congruence between clinical remission and biologic remission, an issue that will need to be addressed in future studies" in order

[7] The NEJM's "painstaking" peer review process "prevent[s] overstated results" and results in the publication of only "about 5%" of "thousands of research reports submitted each year." Publication Process, NEJM.org, https://www.nejm.org/media-center/publication-process (last visited Feb. 6, 2019).

to confirm GED-0301's "impressive clinical effects." *Id.* at 1167.

Market analysts also recognized the Phase II study's lack of an endoscopic endpoint. For example, in a March 18, 2015 report, SunTrust Robinson Humphrey stated that, though the Phase II results were generally "impressive," the Phase II study's failure to match CDAI and endoscopic results was a "shortcoming[]." Ex. 7 (3/18/15 SunTrust Report) at 1, 2; *see also* Compl. ¶ 144. The report stated that "[w]e believe [Celgene] is working to address these issues with a [Phase Ib] study (matching CDAI and endoscopy) ahead of the launch of two Phase III trials in mid-15." Compl. ¶ 144.

3. Celgene Begins Its Phase Ib Study of GED-0301.

On April 8, 2015, Celgene began its Phase Ib study to provide the endoscopic evidence that was missing from Nogra's Phase II study. *See* Compl ¶¶ 144–46. On April 30, 2015, during an earnings call, Celgene advised that "[w]e are aggressively moving clinical development plans forward" for GED-0301, and that "[a] registration-enabling endoscopy study [the Phase Ib study] is underway." Ex. 8 (4/30/15 Call Tr.) at 9; *see also* Compl. ¶ 143.

Market analysts continued to note the lack of an endoscopic endpoint in the Phase II study. In a May 18, 2015 report, for example, SunTrust Robinson Humphrey noted that "key investor questions post Phase II data presentations revolved around the lack of endoscopic validation of CDAI improvement." Compl. ¶ 149. According to the report, Celgene was "addressing this question" with the

Phase Ib study. *Id.*

While the Phase Ib study was underway, Celgene continued to express optimism about the prospects for GED-0301 based on the Phase II data. *See* Compl. ¶¶ 143, 146-156. Celgene also noted, however, that it would be necessary to "see in Phase III what we saw in Phase II" before concluding that "we have a new standard of care" for Crohn's disease. Ex. 9 (6/10/15 Conf. Tr.) at 7.

4. Celgene Releases Interim Results from the Phase Ib Study, Which Is Widely Noted to Lack a Placebo Control Arm.

On September 12, 2016, Celgene announced interim topline data from the Phase Ib study, which it viewed positively. Comp. ¶ 157; *see also* Ex. 10 (9/12/16 8-K) at 1 ("[W]e are pleased that oral GED-0301 showed both endoscopic improvements and clinically meaningful responses and remissions at an early timepoint in this study."). In doing so, Celgene revealed that the study lacked a placebo control arm. *See* Ex. 10 (9/12/16 8-K) at 2.

Indeed, as the Complaint acknowledges, "[a]t the time Celgene announced the Phase Ib results, some analysts noted that the Phase Ib study lacked a control group, which raised questions about the ability to draw conclusions regarding the study." Compl. ¶ 179. For example, Leerink Partners reported that "there was no control arm for the trial to demonstrate statistical significance or show if the efficacy signal was drug-induced." *Id.*

On October 17, 2016, Celgene announced the interim results from the Phase

Ib study. Ex. 11 (10/17/16 8-K). In the press release, Celgene provided a more detailed description of the study, which again revealed the lack of a placebo control arm. *See id.* at 1. Celgene's press release also reiterated that "[w]e are encouraged that oral GED-0301 showed both improvement and clinical remission at an early timepoint in this study." *Id.* at 2.

During an October 18, 2016 conference call to discuss the Phase Ib data, Celgene stated that it was "very encouraged by the validating results we've seen to date," Compl. ¶ 365, and that the Phase Ib interim trial results "provide a compelling early signal of GED-0103['s] efficacy," *id.* ¶ 367 (capitalization altered). Celgene noted again, however, that whether GED-0301 actually caused "long-term endoscopic remission" would not be known until Phase III results were available. Ex. 12 (10/18/16 Call Tr.) at 12.

Analysts continued to note that, although "the [Phase Ib] data continue to point to a promising new oral therapy for Crohn's disease," the lack of a placebo control arm "makes the data hard to interpret." Ex. 13 (10/18/16 RBC Report) at 1. Indeed, during the October 18, 2016 conference call, a Cohen and Company analyst stated that, "[a]s you guys know, you have been chided a little bit by the investment community for a lack of placebo control in this study," and he questioned whether "there is a true drug effect." Compl. ¶ 181; *see also* Ex. 12 (10/18/16 Call Tr.) at 6 (RBC Capital Markets analyst noting the lack of a placebo control arm). Further, given the lack of a placebo control arm in the Phase Ib study, analysts understood that

"ultimately the Phase III data with full one-year timepoint will [be needed to] give the complete picture (readout early '18)." Ex. 13 (10/18/16 RBC report) at 1.

5. Celgene Begins the Phase III Trial for GED-0301.

On December 8, 2016, while the Phase Ib trial was still ongoing, Celgene began the Phase III trial for GED-0301. Compl. ¶ 184. According to the Complaint, "[t]he trial enrolled 701 patients across 538 study locations, and was designed to test GED-0301 compared to a placebo for a period of 52 weeks using both clinical and endoscopic measures of remission and response." *Id.* The Phase III study was expected to take two or more years to complete. *Id.* Celgene told investors that "potential approval" for the drug could occur in 2019. *Id.* ¶¶ 196–98.

As a part of the Phase III trial, Celgene established a Data Monitoring Committee (the "DMC"), which "is an independent committee established as part of large Phase III trials and which is typically comprised of clinicians with expertise in the relevant field being studied, and at least one biostatistician knowledgeable about statistical methods for clinical trials." *Id.* ¶ 200 n.10. As the Phase III trial progressed, the DMC was "given access to unblinded study data in order to assess the safety and futility of completing [the] Phase III trial." *Id.*

6. Celgene Warned Investors That the Phase III Trial May Not Lead to Regulatory Approval.

At various healthcare conferences in September 2017, Celgene reiterated that it was targeting 2019 for the "potential approval" of GED-0301 by the FDA. Compl.

¶¶ 196–98. These statements were made with specific reference to the risk disclosures contained in Celgene's Form 10-K filed in February 2017. Ex. 16 (9/6/17 Pres'n) at 2; Ex. 54 (9/14/17 Pres'n) at 2; Ex. 55 (9/26/17 Pres'n) at 2. That 10-K expressly identified "risks to obtaining and maintaining regulatory approvals" for GED-0301 and other drugs:

> In general, preclinical tests and clinical trials can take many years and require the expenditure of substantial resources, and the data obtained from these tests and trials may not lead to regulatory approval; [and]
>
> Delays or rejections may be encountered during any stage of the regulatory process if the clinical or other data fails to demonstrate compliance with a regulatory agency's requirements for safety, efficacy and quality[.]

Ex. 14 (2/10/17 10-K) at 17.

7. Celgene Stops the Phase III Trial Based on the DMC's Recommendation.

In October 2017, the DMC recommended discontinuing the Phase III trial. Compl. ¶ 200. On October 19, 2017, Celgene announced that—based on the recommendation of the DMC, "which assessed overall benefit/risk [of GED-0301] during a recent interim futility analysis"—it had decided to discontinue the Phase III trial for GED-0301. *Id.* ¶¶ 200, 468. The day after this announcement, Celgene's stock price declined $14.63 per share, from $135.96 to $121.33. *Id.* ¶ 202.

B. Argument

Plaintiff's Section 10(b) claim regarding GED-0301 contends that Defendants misrepresented "the evidence of GED-0301's efficacy, including the strength of the Phase II clinical data and the design of the Phase Ib study, and the timeline for GED-

0301's regulatory approval." Compl. ¶ 342; *see also id.* ¶ 12. According to Plaintiff, "Celgene never had data showing, with any defensible scientific analysis, that GED-0301 worked." *Id.* ¶ 13.

To state a claim under Section 10(b) and Rule 10b-5, "a plaintiff must plead: (1) a material misrepresentation in connection with the purchase or sale of a security; (2) scienter, *i.e.*, a wrongful state of mind in the party making the representation; (3) reliance by the plaintiff; (4) economic loss; and (5) 'loss causation, *i.e.*, a causal connection between the material misrepresentation and the loss.'" *OFI Asset Mgmt. v. Cooper Tire & Rubber*, 834 F.3d 481, 493–94 (3d Cir. 2016) (quoting *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 341–42 (2005)). Rule 9(b) applies to the claim, and a failure to plead any element with particularity requires dismissal. *See, e.g.*, *Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 144–45 (3d Cir. 2004). In addition, Plaintiff also must satisfy the PSLRA's heightened pleading rules, which require (among other things) "stat[ing] with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). Plaintiff has failed to meet these pleading requirements.

1. Defendants' Statements About GED-0301's Phase II and Phase Ib Data Are Not Actionable.

Plaintiff claims that Defendants' statements about GED-0301's Phase II and Phase Ib data were materially false or misleading, because (1) the Phase II data "did not provide endoscopic confirmation of whether GED-0301 was having a positive

effect on patients," and (2) the Phase Ib study lacked "a placebo control arm," a "design flaw [that] prevented any apparent efficacy results from being attributed to GED-0301 versus some other cause." *Id.* ¶¶ 16, 22. None of Defendants' statements about the Phase II and Phase Ib trials, however, is actionable.

a. The Phase II and Phase Ib Study Results Were Fully Disclosed to the Market.

Defendants' characterizations of the Phase II and Phase Ib test results are not actionable because those results, including the purported problems with the studies—the Phase II study's lack of "endoscopic confirmation," and the Phase Ib study's lack of a "placebo control arm," Compl. ¶¶ 16, 22—were all *fully disclosed* to investors. The Complaint itself makes this clear, as do documents the Complaint references. *See, e.g.*, Compl. ¶¶ 17–18, 135, 136, 138, 144, 179, 181.

As courts have held—on motions to dismiss—a defendant's "conclusions . . . [and] other characterizations" about "publicly available data" are "not actionable" as a matter of law. *In re Sanofi-Aventis Sec. Litig.*, No. 07-cv-10279, 2009 WL 3094957, at *5 (S.D.N.Y. Sept. 25, 2009). Such "subjective statements are not materially false" because "the objective data underlying those statements [has been] disclosed to the public." *Maiman v. Talbott*, No. 8:09-cv-12, 2010 WL 11421950, at *4 (C.D. Cal. Aug. 9, 2010); *see also City of Roseville Emps.' Ret. Sys. v. Sterling Fin. Corp.*, 963 F. Supp. 2d 1092, 1130–31 (E.D. Wash. 2013) (rejecting claim in light of "disclosure of the data underlying [the] representation"), *aff'd*, 691 F. App'x 393 (9th Cir. 2017); *Abuhamdan v.*

Blyth, Inc., 9 F. Supp. 3d 175, 200 (D. Conn. 2014) (explaining that "an expression of opinion is not actionable" when "the information underlying it is publicly available").

Thus, in *In re Sanofi Securities Litigation*, 87 F. Supp. 3d 510, 539 (S.D.N.Y. 2015), *aff'd sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016), the court dismissed a Section 10(b) claim that Sanofi executives had misleadingly lauded clinical trial results even though the FDA had expressed concern to Sanofi about the trial's "single-blind study design." Because "the FDA had publicly stated . . . its preference for double-blind studies," and because Sanofi's single-blind design was detailed in "articles published in prominent medical journals" and also in "[p]ress releases," the court held that the executives' characterizations of the study were not actionable. *Id.* at 539–41.

Similarly, in *Sanofi-Aventis*, the court dismissed a Section 10(b) claim that alleged the drug company had misled investors about a new obesity drug in clinical trials. Although the company had described the drug's "negative side effects as 'relatively mild and self-limiting,'" the FDA expressed "concerns" about them and "rejected approval" of the drug. 2009 WL 3094957, at *2, *5. But the court held that investors could not have been misled by the company's "characterizations" of the side effects, because the underlying "study data was made available to the public through [the company's] press releases, S.E.C. filings, and various medical publications." *Id.* at *5.

Further examples abound. In *Kleinman v. Elan Corp.*, the Second Circuit affirmed the dismissal of a claim that the defendant had misleadingly described Phase II clinical trial results as "encouraging," because the defendant had disclosed its

methodology, which was all that the plaintiff claimed was improper. 706 F.3d 145, 154–55 (2d Cir. 2013). In *City of Roseville*, the court held that the defendant's description of itself as "well-capitalized"—even if potentially "misleading" on its own—could not be actionable when the defendant published its underlying financials in a press release. 963 F. Supp. 2d at 1131. And in *Abuhamdan*, the court held that the defendants' characterizations of their company's turnover rate were not actionable when the underlying "raw numbers . . . had been revealed to the market." 9 F. Supp. 3d at 200; *see also, e.g.*, *In re EDAP TMS S.A. Sec. Litig.*, No. 14-cv-6069, 2015 WL 5326166, at *11 (S.D.N.Y. Sept. 14, 2015); *Gregory v. ProNAi Therapeutics, Inc.*, 297 F. Supp. 3d 372, 411–12 (S.D.N.Y. 2018); *Maiman*, 2010 WL 11421950, at *4.

In these cases and others, when data has been disclosed, there is no basis for a claim that the defendants misled investors about that data. Accordingly, Plaintiff's Section 10(b) claim regarding GED-0301 fails to the extent it is based on Defendants' characterizations of the Phase II and Phase Ib data.[8]

[8] Relatedly, Plaintiff also has not adequately alleged the "causal link between the alleged misconduct and the economic harm ultimately suffered," *Abuhamdan*, 9 F. Supp. 3d at 207—here, between Defendants' alleged misstatements about GED-0301's Phase II and Phase Ib data and the October 2017 stock drop. The stock drop was allegedly caused by the announcement that Celgene was stopping the Phase III trial. *See* Compl. ¶ 200. That announcement did not reveal the "truth" about any of the alleged problems with the Phase II and Phase Ib studies; as discussed, that "truth" was public long before October 2017. Plaintiff's failure to allege loss causation also warrants dismissal of the Section 10(b) claim to the extent it is based on Defendants' characterizations of the Phase II and Phase Ib data. *See, e.g.*, *Martin v. GNC Holdings, Inc.*, No. 15-cv-1522, 2017 WL 3974002, at *19 (W.D. Pa. Sept. 8, 2017) (finding loss causation inadequately pleaded); *Abuhamdan*, 9 F. Supp. 3d at 209 (same).

b. Plaintiff Targets General Statements of Optimism That Are Nonactionable Puffery.

In addition, Plaintiff largely targets Defendants' statements about the Phase II and Phase Ib data being "striking," "spectacular," or "incredible," or Celgene being "very excited" or "encouraged" by the data, and so on. *See, e.g.*, Compl. ¶¶ 343–48, 351–55, 359, 361, 364–65, 367–68, 372. These are precisely "the kind of 'vague and general statement[s] of optimism' that 'constitute[] no more than puffery and [are] understood by reasonable investors as such.'" *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 172 (3d Cir. 2014) (quoting *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 538 (3d Cir. 1999)). Such statements are nonactionable as a matter of law. *See id.*

For example, the Third Circuit has held that the use of the adjectives "spectacular" and "breakthrough" is "not actionable"—and, similarly, that the statement that a drug "offer[s] opportunities for transformational growth" is "vague [and] non-specific." *Id.* at 172–73.[9] Defendants' characterizations of the Phase II and Phase Ib data are no different.

[9] Other courts have also held that similar statements are nonactionable puffery. *See, e.g.*, *Kleinman*, 706 F.3d at 153 (addressing "words like 'encouraging'"); *Galati v. Commerce Bancorp, Inc.*, 220 F. App'x 97, 102 (3d Cir. 2007) (addressing "statements concerning the Company's 'dramatic deposit growth,' 'strong performance,' and 'unique business model'"); *Bauer v. Eagle Pharm., Inc.*, No. 16-cv-3091, 2017 WL 2213147, at *12 (D.N.J. May 19, 2017) (addressing "statements that the Product is 'unique,' 'far superior' to other generic drugs, should do 'very well' and will be 'well received'"); *In re Neurotrope, Inc. Sec. Litig.*, 315 F. Supp. 3d 721, 733–34 (S.D.N.Y. 2018) (addressing statement that defendant was "pretty excited about [its] upcoming Phase 2 top-line data").

c. Defendants' Characterizations of the Phase II and Phase Ib Data Are Nonactionable Opinions.

Defendants' statements about the Phase II and Phase Ib data also are nonactionable because "[i]nterpretations of clinical data are considered opinions," which "are only actionable under the securities laws if they are not honestly believed and lacked a reasonable basis." *City of Edinburgh*, 754 F.3d at 170.[10] Thus, a plaintiff can maintain a claim about an opinion only if the complaint alleges that the speaker did not actually hold the opinion. *See, e.g.*, *Hoey v. Insmed, Inc.*, No. 16-cv-4323, 2018 WL 902266, at *16 (D.N.J. Feb. 15, 2018); *In re Amarin Corp. PLC Sec. Litig.*, 689 F. App'x 124, 132 (3d Cir. 2017). The Complaint, however, lacks any such allegation.

Moreover, even if Plaintiff had alleged that Defendants did not honestly view the Phase II and Phase Ib data positively, Defendants' opinions still would not be actionable unless those opinions additionally "lacked a reasonable basis." *City of Edinburgh*, 754 F.3d at 170. But Plaintiff cannot plausibly allege that Defendants' optimism about the Phase II data was unreasonable when, for example, Dr. Sandborn—whom Plaintiff describes as an "authority" in the field (Compl. ¶ 169)—viewed the results as "exciting." Ex. 15 (Walsh Art.) at 3. Similarly, in her NEJM editorial, Dr. Vermeire called the data "impressive" and "unprecedented." Ex. 6

[10] *City of Edinburgh* remains controlling on this issue notwithstanding *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S. Ct. 1318 (2015). *See, e.g.*, *Hoey v. Insmed, Inc.*, No. 16-cv-4323, 2018 WL 902266, at *16 n.14 (D.N.J. Feb. 15, 2018); *see also Jaroslawicz v. M&T Bank Corp.*, 912 F.3d 96, 113 (3d Cir. 2018). In any event, the opinion statements here are nonactionable even under *Omnicare*.

(Vermeire Art.) at 1166–67. As for the Phase Ib data, Plaintiff does not dispute that Phase Ib patients showed an endoscopic response, and contests only the import of that data.[11] But Dr. Sandborn also viewed the Phase Ib data positively, stating that "[t]hese data support the notion that GED-0301, a potential first-in-class oral antisense therapy, may target an underlying cause of Crohn's disease, rather than improving symptoms." Ex. 10 (9/12/16 8-K) at 1. Plaintiff's claim cannot withstand these and other similar statements. *See, e.g.*, *City of Edinburgh*, 754 F.3d at 170 (holding that defendants' opinions about Phase II data were not actionable where there was at least some "circumstantial evidence of efficacy"); *In re Amarin Corp. PLC Sec. Litig.*, No. 13-cv-6663, 2016 WL 1644623, at *14 (D.N.J. Apr. 26, 2016) (granting motion to dismiss claim that defendants were misleadingly optimistic about clinical study where plaintiff failed to allege "facts demonstrating that the . . . study was not, at least in some manner, indicative of the [drug's] efficacy").[12]

[11] One confidential witness allegedly saw "no endoscopic response" for two patients who completed the study. Compl. ¶ 172. The study, however, had 63 enrollees, Ex. 10 (9/12/16 8-K) at 1, and the witness does not speak to how others responded.

[12] Even if others at Celgene might have disagreed with Defendants' characterizations of the Phase II and Phase Ib data, "the disagreement of [several] employees within a large pharmaceutical company about the interpretation of clinical trial data . . . does not render defendants' decisions unreasonable or their statements false." *City of Edinburgh*, 754 F.3d at 171; *see also, e.g.*, *Gregory*, 297 F. Supp. 3d at 417 n.29. A company has "no obligation to second-guess the methodology of [a] study" so long as it "accurately reports the results." *In re Adolor Corp. Sec. Litig.*, 616 F. Supp. 2d 551, 567 (E.D. Pa. 2009) (quoting *Padnes v. Scios Nova Inc.*, No. 95-cv-1693, 1996 WL 539711, at *5 n.1 (N.D. Cal. Sept. 18, 1996)).

2. Defendants' Statements About the Projected Timeline for GED-0301's Potential Regulatory Approval Are Not Actionable.

Plaintiff also targets Defendants' statements about "the timeline for GED-0301's regulatory approval," Compl. ¶ 342; *see also, e.g.*, *id.* ¶¶ 195, 374, 376–79, Plaintiff alleges these statements were false or misleading because, "by July 2017," Celgene had decided that GED-0301 would be "scrapped." *Id.* ¶ 29. None of these statements is actionable.

a. Most of Defendants' Statements Are Protected by the PSLRA's Safe Harbor for Forward-Looking Statements.

The PSLRA defines a "forward-looking statement" to include any "statement[s] of the plans and objectives of management for future operations." § 78u-5(i)(1)(B). "[S]tatements about FDA approval are classically forward-looking—they address what defendants expected to occur in the future." *Sanofi*, 87 F. Supp. 3d at 535. Under the PSLRA, such statements (if identified as forward-looking) are immune from liability if either (1) they were "accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement," or (2) the speaker lacked "actual knowledge . . . that the statement was false or misleading." § 78u-5(i)(1)(B); *see also* § 78u-5(c)(2)(A)–(B) (addressing oral statements).[13]

[13] These are independent grounds for dismissal. Meaningful cautionary language precludes liability for forward-looking statements regardless of what else is alleged.

(i) Plaintiff Targets Forward-Looking Statements About GED-0301's Projected Approval Date.

Plaintiff inexplicably alleges that "[n]one of the statements complained of herein was a forward-looking statement." Compl. ¶ 537. But Defendants' September 2017 statements about GED-0301's progress towards regulatory approval were plainly forward-looking in nature. *See, e.g.*, *id.* ¶¶ 376, 378, 379 (targeting presentation slide listing "2019" for GED-0301's "Potential Approval"). They were also identified as forward-looking statements when made. *See, e.g.*, Ex. 16 (9/6/17 Pres'n) at 2.

(ii) Defendants' Forward-Looking Statements Were Accompanied by Meaningful Cautionary Language.

"Cautionary statements disclosed in SEC filings may be incorporated by reference" into a forward-looking statement, instead of needing to be repeated each time. *In re Aetna Inc. Sec. Litig.*, 617 F.3d 272, 282 (3d Cir. 2010). Defendants' forward-looking statements about GED-0301's projected approval date incorporated the cautionary statements set forth in Celgene's then-current Form 10-K, which was filed on February 10, 2017. *See, e.g.*, Ex. 16 (9/6/17 Pres'n) at 2.

Celgene's cautionary language was plainly meaningful. Instead of being some "blanket (boilerplate) disclaimer which merely warns the reader that the investment has risks," *Institutional Inv'rs Grp. v. Avaya*, 564 F.3d 242, 256–58 (3d Cir. 2009), the

See OFI Asset Mgmt., 834 F.3d at 502. Similarly, a lack of "actual knowledge" of falsity by the speaker always precludes liability. *See id.*

cautionary language described the exact risk that ultimately materialized with GED-0301: the drug's "tests and trials may not lead to regulatory approval." Ex. 14 (2/10/17 10-K). This cautionary language precludes liability for Defendants' statements in September 2017 about the timeline for GED-0301's potential regulatory approval. *See, e.g.*, *In re Nuvelo, Inc., Secs. Litig.*, No. 07-cv-4056, 2008 WL 5114325, at *16 (N.D. Cal. Dec. 4, 2008) (holding that safe harbor protected statements about potential success of drug that still needed to go through Phase III clinical trials); *Harrington v. Tetraphase Pharm., Inc.*, Nos. 16-10133-LTS, 16-10577-LTS, 2017 WL 1946305, at *9 (D. Mass. May 9, 2017) (holding that safe harbor protected statements about timeline for regulatory submission).

(iii) Defendants' Forward-Looking Statements Were Not Made With Actual Knowledge of Their Falsity.

Alternatively, even if Celgene's cautionary language were not adequate, Plaintiff has not alleged that Defendants made their forward-looking statements about GED-0301's potential regulatory approval date with "actual knowledge of [the statement's] falsehood," as the PSLRA separately requires. *Williams v. Globus Medical, Inc.*, 869 F.3d 235, 245 (3d Cir. 2017); *see* §§ 78u-4(b)(2)(A), 78u-5(c)(1)(B). This standard requires alleging "knowing deception" with particularity, which Plaintiff has not come close to doing. *Avaya*, 564 F.3d at 274.

Indeed, Plaintiff's claim that Defendants misrepresented the timeline for GED-0301's potential approval rests entirely on the claim that Celgene had decided by the

summer of 2017 that the drug would be "scrapped." Compl. ¶ 29. But the only basis for this bold allegation is the speculative hearsay of two confidential witnesses, identified as "FE 4" and "FE 6." *Id.* ¶¶ 192–94. Even if credited, these hearsay allegations cannot show Defendants had actual knowledge that GED-0301 would be "scrapped," because neither FE 4's nor FE 6's views is alleged to have been shared by (or, for that matter, even conveyed to) Defendants Kellogg or Ahmed, who made the September 2017 statements in question.

In any event, the allegations about FE 4 and FE 6 deserve little (if any) weight. Courts have widely called for caution when plaintiffs rely on confidential sources in securities fraud suits. "[U]nnamed confidential sources . . . may be ill-informed, may be acting from spite rather than knowledge, may be misrepresented, may even be nonexistent—a gimmick for obtaining discovery costly to the defendants and maybe forcing settlement or inducing more favorable settlement terms." *City of Livonia Empls.' Ret. Sys. v. Boeing Co.*, 711 F.3d 754, 759 (7th Cir. 2013). Indeed, "[n]umerous reported decisions have recounted claims by [confidential sources] that such complaints inaccurately attributed facts and statements to them." *In re Millenial Media, Inc. Sec. Litig.*, No. 14-cv-7923, 2015 WL 3443918, at *12 (S.D.N.Y. May 29, 2015) (collecting cases).

Thus, as the Third Circuit has instructed for motions to dismiss, "when dealing with confidential witnesses, courts should assess the 'detail provided by the confidential sources, the sources' basis of knowledge, the reliability of the sources, the

corroborative nature of other facts alleged, including from other sources, the coherence and plausibility of the allegations, and similar indicia.'" *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 244 (3rd Cir. 2013) (quoting *Avaya*, 564 F.3d at 261). "If, after that assessment, 'anonymous source allegations are found wanting with respect to these criteria . . . [courts] must discount them steeply.'" *Id.* (quoting *Avaya*, 564 F.3d at 263).

Under the Third Circuit's standard, one important factor is whether a confidential witness's "supposed knowledge is first or second hand." *Chubb*, 394 F.3d at 150. Applying this test, courts have rejected hearsay "allegations [that] present third-hand information" through confidential sources—recognizing that such "she-said-that-he-said-that-she-said" allegations offer little probative value. *In re PDI Sec. Litig.*, No. 02-cv-211, 2006 WL 3350461, at *27 (D.N.J. Nov. 16, 2006) (granting motion to dismiss).

Notably, FE 4 is not alleged to have had any involvement in the supposed decision to end the Phase III trial early. Instead, FE 4 supposedly learned from Gerald Horan ("Horan") in June 2017 that the Phase III trial "was going to be 'scrapped.'" Compl. ¶ 192. But Horan also had no involvement in this purported decision, and only was allegedly "in a position to access the information regarding the ongoing Phase III GED-0301 trial"—specifically "pharmacological data that could be extrapolated to determine whether GED-0301 was having the desired effect." *Id.* Besides this vague allegation of "access" (which Horan is not even alleged to have

used) to raw "pharmacological data," Plaintiff does not explain *how* Horan learned the Phase III trial's purported fate—much less whose view Horan conveyed to FE 4. *See id.* ¶¶ 192-93. Such confidential allegations "based upon rumor and conjecture are undisputedly insufficient to satisfy" Plaintiff's pleading burden. *Chubb*, 394 F.3d at 155 (affirming dismissal); *see also, e.g.*, *Rahman*, 736 F.3d at 244 (same); *Martin v. GNC Holdings, Inc.*, No. 15-cv-1522, 2017 WL 3974002, at *12 (W.D. Pa. Sept. 8, 2017) (granting motion to dismiss).[14]

The allegations regarding FE 6 fare no better. Plaintiff claims that FE 6 "was informed by a Celgene colleague"—who is not named—"in the summer of 2017 that the GED-0301 Phase III clinical trial would be discontinued." Compl. ¶ 194. According to Plaintiff, FE 6's unnamed colleague attended a meeting in August 2017 at which other attendees discussed the Phase III trial. *Id.* These layers of anonymous hearsay, with no allegation about how the colleagues of FE 6's colleague's even learned about the double-blinded Phase III trial's status, deserve little if any weight. *See, e.g.*, *PDI*, 2006 WL 3350461, at *27; *Utesch v. Lannett Co.*, 316 F. Supp. 3d 895, 904 (E.D. Pa. 2018) (granting motion to dismiss where confidential witness did not adequately "explain the source of his knowledge").

Moreover, the idea that Celgene decided to stop the Phase III trial *four months*

[14] FE 4's separate assertion that "Celgene had effectively given up on GED-0301 after the Phase Ib study" is similarly too vague: FE 4 merely did not "recall" GED-0301 being mentioned during internal quarterly review meetings (exactly which?) of Celgene's Vice Presidents (who?), which FE 4 found "unusual." Compl. ¶ 187.

before actually doing so is also deeply implausible on its face. Phase III trials are very costly, and the Complaint offers no explanation for why Celgene would keep running a trial despite having (supposedly) concluded that it was futile. This gives additional reason to doubt the anonymous hearsay from FE 4 and FE 6, which is all that supports Plaintiff's claim for statements about the timeline for GED-0301's potential regulatory approval. *See, e.g.*, *Rahman*, 736 F.3d at 244 (must consider "coherence and plausibility" of anonymous claims).

b. Defendants' Statements Are Not Actionable Even Without the PSLRA Safe Harbor.

Even without the safe harbor, Defendants' statements about the timeline for GED-0301's potential regulatory approval—whether forward-looking or not—are not actionable. All of these statements are opinions, but there is no allegation that they were not honestly believed by the speaker. *See City of Edinburgh*, 754 F.3d at 170. Indeed, Plaintiff fails to connect the anonymous allegations from FE 4 and FE 6 to Curran, Alles, Kellogg, or Ahmed, who made the alleged misstatements about GED-0301's timeline. *See* Compl. ¶¶ 195, 374–79.

Separately, Plaintiff has not alleged that Defendants' statements of opinion lacked a reasonable basis when made. *See City of Edinburgh*, 754 F.3d at 170. As noted, Defendants had a reasonable basis to be optimistic about the drug after the Phase II and Phase Ib trials, and little if any weight is due to the anonymous claims of FE 4 and FE 6 that the drug's prognosis changed in advance of the DMC's

recommendation in October 2017.

3. Plaintiff's Allegations Do Not Give Rise to a Strong Inference of Scienter.

Plaintiff also has failed to allege facts giving rise to a "strong inference" of scienter for any of Defendants' statements regarding GED-0301. Assessing scienter requires "consider[ing] plausible, nonculpable explanations for the defendant's conduct." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007). The allegations must produce an inference of scienter that is "more than merely 'reasonable' or 'permissible'"—it must be "cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.*

Scienter for purposes of securities fraud is a state of mind "'embracing [an] intent to deceive, manipulate, or defraud,' either knowingly or recklessly," *In re Hertz Global Holdings Inc.*, 905 F.3d 106, 114 (3d Cir. 2018) (quoting *Avaya*, 564 F.3d at 252). "A reckless statement is one 'involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers and sellers that is either known to the defendant or so obvious that the actor must have been aware of it.'" *Advanta*, 180 F.3d at 535 (quoting *McLean v. Alexander*, 599 F.2d 1190, 1197 (3d Cir. 1979)). This standard is "demanding." *Globis Capital Partners, L.P. v. Stonepath Grp., Inc.*, 241 F. App'x 832, 835 (3d Cir. 2007).

In addition, "[t]he PSLRA requires plaintiffs to specify the role of each

defendant, demonstrating each defendant's involvement in misstatements and omissions." *Winer Family Trust v. Queen*, 503 F.3d 319, 335–36 (3d Cir. 2007). "Generalized imputations of knowledge do not suffice, regardless of the defendants' position within the company." *Advanta*, 180 F.3d at 539.

a. Plaintiff's Allegations Actually Cut Against an Inference of Scienter for Defendants' Statements About the Phase II and Phase Ib Data.

Far from supporting a strong inference of scienter, Plaintiff's allegations show that Defendants did *not* intend to defraud investors about GED-0301. At a minimum, the possibility of fraud is not nearly "as compelling" as the likelihood that Defendants acted innocently (or, at worst, negligently). *Tellabs*, 551 U.S. at 314.

As noted, the Phase II and Phase Ib studies' results and purported weaknesses were fully disclosed to investors. *See supra* Part II.B.1.a. "It defies logic to conclude that executives who are seeking to perpetrate fraudulent information upon the market would make such fulsome disclosures. If [the] executives sought to shield investors from 'learning the truth of' [their] business, they needed to be measurably more opaque." *Kuriakose v. Fed. Home Loan Mortg. Corp.*, 897 F. Supp. 2d 168, 185 (S.D.N.Y. 2012), *aff'd*, 543 F. App'x 72 (2d Cir. 2013); *see also Kelley v. Aerie Pharm.*, No. 15-cv-3007, 2016 WL 3437603, at *9 (D.N.J. June 20, 2016) (dismissing on scienter grounds where defendant put a "positive spin on [Phase IIb] results" but also released the "actual results").

Moreover, Celgene made a record upfront payment of $710 million for the

rights to GED-0301 based on the Phase II trial results. It defies common sense that the company would have paid so much for GED-0301 if Defendants did not actually believe that the Phase II data supported the drug's efficacy. *See, e.g.*, *Hoey*, 2018 WL 902266, at *21. Similarly, as the Third Circuit has explained, the sheer expense of initiating a Phase III trial "render[s] it improbable that defendants would have continued if they did not believe their interpretation of the interim results or if they thought the drug a complete failure." *City of Edinburgh*, 754 F.3d at 164 at 170; *see also, e.g.*, *Sapir v. Averback*, No. 14-cv-7331, 2016 WL 554581, at *10 (D.N.J. Feb. 10, 2016) (dismissing claim on scienter grounds, rejecting theory that "Defendants knew all along that the Phase 3 studies were unlikely to succeed but concealed this information in order to prolong the viability of the Company"); *Sanofi*, 87 F. Supp. 3d at 544 ("Defendants' substantial investment of money and personnel . . . over a several-year period is hard to square with the premise that defendants understood that the study design was fatally flawed or that the results made [the drug] dead on arrival.").[15]

[15] Plaintiff also alleges that a series of confidential witnesses internally expressed their doubts about the Phase II and Phase Ib studies and data and about GED-0301 more generally. *See, e.g.*, Compl. ¶¶ 118–22, 124, 126, 128–30, 132, 140–41, 154–55, 167–70, 173, 177. But none of these anonymous witnesses' views is alleged with particularity to have been conveyed to a Defendant who made an alleged misstatement about GED-0301. These witnesses thus do not support an inference of scienter. *See, e.g.*, *Winer Family Trust*, 503 F.3d at 335–36; *Advanta*, 180 F.3d at 539.

b. Plaintiff's Anonymous Hearsay Does Not Create a Strong Inference of Scienter for Defendants' Statements About GED-0301's Timeline for Potential Regulatory Approval.

Nor does the anonymous, unsupported hearsay from FE 4 and FE 6 that Celgene had decided to "scrap" the Phase III trial in the summer of 2017 create a strong inference of scienter for Defendants' statements about GED-0301's progress towards regulatory approval.[16] Again, those confidential witnesses' statements are entitled to little or no weight as discussed above. *See supra* Part II.B.2.a.iii.

Even if Plaintiff's anonymous allegations are not steeply discounted, moreover, the facts alleged by FE 4 and FE 6 are still far too flimsy to establish a strong inference of fraud. *See Avaya*, 564 F.3d at 263 n.33 ("[I]t is important to distinguish deficiencies relating to the content of allegations from those relating to their form."). Rumors and innuendo about Celgene's plans for the Phase III trial do not nearly amount to a particularized allegation that Celgene had decided to scrap the Phase III trial. *See Chubb*, 394 F.3d at 155; *Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1069 n.13 (9th Cir. 2008) ("The problem for [plaintiff] is not that the confidential witnesses are inadequately identified—the problem is that these witnesses do not convey information sufficient to support the strong inference of scienter that the PSLRA requires.").

[16] As previously discussed, most of these statements were forward-looking and can be actionable only if made with actual knowledge of their falsity. Plaintiff has not met this burden for the reasons discussed above. *See supra* Part II.B.2.a.

Finally, as noted, the (dubious) views of FE 4 and FE 6 are not alleged to have reached the speakers of the statements at issue. For this reason also, they cannot support an allegation of scienter. *See, e.g.*, *In re Bio-Tech. Gen. Corp. Sec. Litig.*, 380 F. Supp. 2d 574, 596 (D.N.J. 2005) ("Mere allegations of knowledge on the part of subordinates do not provide a sufficient basis for imputing knowledge to executives."); *Chubb*, 394 F.3d at 154 (rejecting scienter allegation based on discussions at alleged meetings when complaint "says nothing with particularity" about "whether any Defendants were in fact present at such a meeting"); *Adolor*, 616 F. Supp. 2d at 574 (rejecting scienter allegation because "it is not clear how [confidential witness] would possess information regarding Defendants' knowledge or intent.").

c. The Stock Sales of Three Defendants Do Not Give Rise to a Strong Inference of Scienter.

Plaintiff also attempts to show scienter through alleged sales of Celgene stock—by Alles on February 6, 2015, by Curran on September 25, 2017, and by Hugin between June 20, 2016 and June 22, 2017—that Plaintiff claims were suspiciously timed. Compl. ¶¶ 513–14. For several reasons, these alleged stock sales do not help Plaintiff.

First, the alleged class period is over three years long. Such "[a] lengthy class period makes it difficult to infer intent from the mere fact of a stock sale"—because "insiders [often] trade at some point during their tenure with a company"—and

"[c]ourts have [thus] regularly concluded that an inference of scienter from insider trading is lessened when . . . the class period is well over a year." *Hertz*, 905 F.3d at 120 (quoting *Yates v. Mun. Mortg. & Equity, LLC*, 744 F.3d 874, 891 (4th Cir. 2014)). Moreover, Alles's transaction was more than "two years before the alleged corrective disclosures," which "defeats any inference of scienter."' *Martin*, 2017 WL 3974002, at *15 (quoting *In re Party City Sec. Litig.*, 147 F. Supp. 2d 282, 313 (D.N.J. 2001)).

Second, the Third Circuit has also held that an inference of scienter from stock sales is weakened when only a subset of defendants traded stock. *See Hertz*, 905 F.3d at 120. Here, Plaintiff alleges only three individual Defendants traded Celgene stock.

Third, as to the three Defendants who allegedly traded stock, all but one of the identified transactions was made pursuant to a Rule 10b5-1 trading plan. Compl. ¶¶ 520–21. Such trades generally do not give rise to an inference of scienter. *See, e.g.*, *Avaya*, 564 F.3d at 279; *In re Egalet Corp. Sec. Litig.*, 340 F. Supp. 3d 479, 512–13 (E.D. Pa. 2018); *In re NutriSystem, Inc. Derivative Litig.*, 666 F. Supp. 2d 501, 518 n.11 (E.D. Pa. 2009). Plaintiff claims that these trades should nonetheless be viewed suspiciously because it is "quite likely" the Rule 10b5-1 trading plans were set up too late. Compl. ¶ 520. But Plaintiff's mere speculation about when these trading plans were created does not diminish their exculpatory effect. *See Advanta*, 180 F.3d at 540 n.10 (even when "information is not available . . . , [a defendant] has no duty to provide it; rather, the burden is on the plaintiffs to plead facts supporting an inference of scienter"); *NutriSystem*, 666 F. Supp. 2d at 518 n.11 (dismissing complaint where plaintiff "failed

to plead facts suggesting that the 10b5-1 plans were adopted" improperly).

Only Hugin's sale on June 22, 2017 was not covered by a Rule 10b5-1 trading plan, and it represented at most 3.6% of his holdings, per Plaintiff's math. *See* ¶¶ 514 n.16, 521. That figure is too small to suggest scienter. *See Hertz*, 905 F.3d at 120–21 (selling 17% or less of holdings generally does not suggest scienter).

Finally, the three Defendants who sold stock are not alleged to have liquidated all of their holdings in Celgene during the Class Period, and thus, like all other shareholders, they suffered losses when Celgene's stock price declined after the "truth" about the alleged fraud was purportedly revealed. This also "weighs against a strong inference of scienter." *In re Columbia Labs., Inc. Sec. Litig.*, No. 12-cv-614, 2013 WL 10914123, at *4 n.10 (D.N.J. June 11, 2013).[17]

For all these reasons, the stock sales of Alles, Curran, and Hugin do not suggest *any* impropriety, much less a strong inference of fraudulent intent. And regardless, the stock sales do not suggest scienter for any other individual Defendant.

d. Plaintiff's Other Allegations Do Not Establish a Strong Inference of Scienter.

Plaintiff also attempts to show scienter for Defendants' GED-0301 statements

[17] Plaintiff also ignores that Celgene repurchased *billions of dollars'* worth of its stock during the Class Period, *i.e.*, when Plaintiff alleges Defendants were artificially inflating Celgene's stock price due to their alleged fraud. *See, e.g.*, Ex. 17 (2/11/16 10-K) at 32; Ex. 14 (2/10/17 10-K) at 31; Ex. 18 (2/7/18 10-K) at 32. "It is unreasonable to assume that [Celgene] would artificially inflate its stock price when it was repurchasing a significant amount of its own shares on the open market." *Turner v. magicJack VocalTec, Ltd.*, No. 13-cv-448, 2014 WL 406917, at *11 (S.D.N.Y. Jan. 29, 2014).

by noting that Defendant Smith and another employee, George Golumbeski ("Golumbeski"), left Celgene in April 2018, about six months after Celgene stopped the Phase III trial. *See* Compl. ¶¶ 525-26. As the Third Circuit has explained, however, employee departures can "strengthen an inference of scienter" only when "particularized allegations connect[] the departures to the alleged fraud." *Hertz*, 905 F.3d at 118. No such allegations are presented here.[18]

In addition, Plaintiff claims that GED-0301 fell within Celgene's "core operations" and that Defendants thus "must have been aware of all material facts" about the drug. Compl. ¶ 509–10. But this argument flouts the rule against "[g]eneralized imputations of knowledge" (not to mention the PSLRA's particularity requirements). *Advanta*, 180 F.3d at 539. Pleading scienter through "management's general awareness" of a matter requires "additional allegations of specific information conveyed to management and related to fraud." *Rahman*, 736 F.3d at 246–47 (quoting *Metzler*, 540 F.3d at 1068). Plaintiff offers no such allegations.

III. PLAINTIFF'S SECTION 10(B) CLAIM REGARDING OTEZLA SHOULD BE DISMISSED.

A. Factual Background

1. Celgene Launches Otezla and Projects Future Sales.

Otezla is an oral medication that the FDA approved in March 2014 for the treatment of psoriatic arthritis. Compl. ¶ 206. Celgene began selling the drug in the

[18] Indeed, Golumbeski is not alleged to have played any role in the purported fraud.

second quarter of 2014. *Id.* Later that year, in September, the FDA additionally approved Otezla for the treatment of psoriasis. *See* Ex. 19 (9/23/14 PR) at 1.

On January 13, 2014, as Celgene prepared to launch Otezla, it projected "financial targets" for 2017 of $13–$14 billion in total product sales, including $1.5–$2 billion in projected Otezla sales. *See* Compl. ¶ 206; Ex. 20 (1/13/14 8-K) at 2–3.

Otezla sales in 2014 totaled $70 million. *See* Ex. 21 (1/12/15 8-K) at 1. In a January 12, 2015 press release announcing that figure, Celgene also provided a five-year strategic growth plan in which Celgene "reaffirm[ed]" its "2017 financial targets," including the previously projected Otezla sales. *See id.* at 2; Compl. ¶ 207. This plan also included financial targets for 2020, in which total net product sales were projected to exceed $20 billion. *See* Ex. 21 (1/12/15 8-K) at 2.

In the January 2015 press release, Celgene expressly warned that its financial targets were inherently risky and uncertain for reasons detailed in SEC filings:

> This press release contains forward-looking statements . . . . We undertake no obligation to update any forward-looking statement in light of new information or future events, except as otherwise required by law . . . . Forward-looking statements involve inherent risks and uncertainties, most of which are difficult to predict and are generally beyond our control. Actual results or outcomes may differ materially from those implied by the forward-looking statements as a result of the impact of a number of factors, many of which are discussed in more detail in our Annual Report on Form 10-K and our other reports filed with the [SEC].

Id. at 4.

In turn, Celgene's then-current Form 10-K (for 2013) specifically stated "that a number of important factors could cause actual results or outcomes to differ

materially from those expressed in, or implied by, the forward-looking statements, and therefore you should not place too much reliance on them." Ex. 22 (2/13/14 10-K) at 15. The 2013 Form 10-K, which was current at the time, then detailed the following risk factors:

> Sales of our current and future products depend, in large part, on the conditions under which our products are paid for by health maintenance, managed care, pharmacy benefit and similar health care management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payers. . . . Our products continue to be subject to increasing price and reimbursement pressure due to price controls imposed by governments in many countries; increased difficulty in obtaining and maintaining satisfactory drug reimbursement rates; and the tendency of governments and private health care providers to favor generic pharmaceuticals. In addition, governmental and private third-party payers and purchasers of our products may restrict access to formularies or otherwise discourage use of our products. Limitations on patient access to our drugs, adoption of price controls and cost-containment measures could adversely affect our business.

Id. at 18.

On February 20, 2015, Celgene filed its Form 10-K for 2014. In it, Celgene both reiterated the above warnings and also specifically identified risks associated with Otezla (collectively, the "Safe Harbor Warnings"). After first noting that, "[c]urrently, our business is largely dependent on the commercial success of [certain drugs] and OTEZLA®," Celgene's 2014 10-K warned that:

> [t]he success of these products depends on acceptance by regulators, key opinion leaders, physicians, and patients as effective drugs with certain advantages over other therapies. A number of factors, as discussed in greater detail below, may adversely impact the degree of acceptance of these products, including their efficacy, safety, price and benefits over

> competing products, as well as the reimbursement policies of third-party payers, such as government and private insurance plans.

Ex. 23 (2/20/15 10-K) at 17.

> The 2014 10-K then detailed risks related to insurance reimbursement:
>
> Sales of our current and future products depend, in large part, on the conditions under which our products are paid for by health maintenance, managed care, pharmacy benefit and similar health care management organizations (HCMOs), or reimbursed by government health administration authorities, private health coverage insurers and other third-party payers. Exclusion of our products from a formulary or HCMO-implemented restrictions imposed upon our products can significantly impact drug usage in the HCMO patient population, and consequently our revenues.

Id. at 19.

> The 2014 10-K also addressed risks posed by Celgene's competitors:
>
> The pharmaceutical and biotechnology industries in which we operate are highly competitive and subject to rapid and significant technological change. Our present and potential competitors include major pharmaceutical and biotechnology companies, as well as specialty pharmaceutical firms . . . . Some of these companies have considerably greater financial, technical and marketing resources than we have, enabling them, among other things, to make greater research and development investments . . . . The pharmaceutical industry has undergone, and is expected to continue to undergo, rapid and significant technological change and we expect competition to intensify as technical advances are made and become more widely known. The development of products or processes by our competitors with significant advantages over those that we are developing could adversely affect our future revenues and profitability.

Id. at 21. These Safe Harbor Warnings appeared in virtually identical form in Celgene's subsequent 10-K filings on February 11, 2016 and February 10, 2017. *See* Ex. 17 (2/11/16 10-K) at 18–19, 22; Ex. 14 (2/10/17 10-K) at 17–18, 21.

2. Otezla Sales Rise Steadily in 2015 and 2016.

Otezla's sales rose consistently through 2015—from $60 million in the first quarter, to $90 million in the second quarter, to $139 million in the third quarter, to $183 million in the fourth quarter. *See* Ex. 24 (4/30/15 10-Q) at 38; Ex. 25 (7/28/15 10-Q) at 40; Ex. 26 (11/5/15 10-Q) at 45; Ex. 27 (1/28/16 8-K) at 5. Midway through the successful 2015 fiscal year, on July 14, Celgene increased its 2020 projections to over $21 billion in total product sales. Ex. 28 (7/14/15 8-K) at 30. Periodically during 2015, Celgene also reaffirmed its 2017 target for Otezla sales. *See, e.g.*, Compl. ¶¶ 384–90. Each time it did so, Celgene referred investors to the Safe Harbor Warnings. Ex. 29 (1/29/15 8-K) at 9; Ex. 30 (3/4/15 Pres'n) at 2, 21; Ex. 31 (5/12/15 Pres'n) at 2, 22; Ex. 32 (6/10/15 Pres'n) at 2, 22; Ex. 33 (9/17/15 Pres'n) at 2, 13; Ex. 34 (11/10/15 Pres'n) at 2, 13.

During 2016, Celgene continued to reaffirm its 2017 target for Otezla sales, again with reference to the Safe Harbor Warnings. *See, e.g.*, Compl. ¶ 392–93, 395, 398; Ex. 35 (4/28/16 Pres'n) at 2; Ex. 36 (5/11/16 Conf. Tr.) at 1; Ex. 37 (10/27/16 Pres'n) at 2. As it did so, sales of Otezla skyrocketed. Just in the first quarter of 2016 alone, Otezla sales were $196 million, a 224% increase year over year. *See* Ex. 38 (4/28/16 8-K) at 2.

On April 28, 2016, Celgene published sales guidance that projected more than $1 billion in Otezla sales for 2016. *See id.* at 3. Celgene surpassed that target, as Otezla sales grew every quarter in 2016—to $242 million in the second quarter, $275

million in the third quarter, and $305 million in the fourth quarter. *See* Ex. 39 (7/28/16 10-Q) at 44; Ex. 40 (10/27/16 10-Q) at 45; Ex. 41 (1/26/17 8-K) at 2. The $1.017 billion in total Otezla sales for 2016 represented a 116% increase from total sales in 2015.

3. Celgene Adjusts Its 2017 Guidance for Otezla Sales.

On January 26, 2017, Celgene adjusted its 2017 sales target for Otezla from the original $1.5–$2 billion to a new projected range of $1.5–$1.7 billion. Compl. ¶ 244. At the same time, Celgene again provided the Safe Harbor Warnings. *See* Ex. 41 (1/26/17 8-K) at 8.

On April 27, 2017, Celgene released its results for the first quarter of 2017. Otezla sales totaled $242 million, which was a year-over-year increase of 24%, but a 20% decrease from the fourth quarter of 2016. *See* Ex. 42 (4/27/17 10-Q) at 36. In a press release issued that same day (which included the Safe Harbor Warnings, *see* Ex. 43 (4/27/17 8-K) at 3), Celgene reaffirmed its adjusted projection for 2017 Otezla sales, Compl. ¶ 405; as explained in a call later that day, Celgene's continued "confidence" in the 2017 Otezla guidance was driven by the "momentum we see in Q2." Ex. 44 (4/27/17 Call Tr.) at 6.

Indeed, Otezla sales in the second quarter of 2017 totaled $358 million, as Celgene reported on July 27, 2017. *See* Ex. 45 (7/27/17 10-Q) at 40. This was the largest-ever quarterly sales figure for Otezla—a 48% increase over the previous quarter. *See id.* That same day, Celgene also reported that it expected "full-year

[Otezla] revenue to be in the lower half of the [$1.5-$1.7 billion] guid[ance] range." Ex. 46 (7/27/17 Call. Tr.) at 6. Again, Celgene gave the Safe Harbor Warnings. *See id.* at 2.

4. Celgene Again Adjusts Its 2017 Guidance for Otezla Sales.

During the third quarter of 2017, some of the risks that Celgene had cautioned about in its Safe Harbor Warnings materialized. Celgene reported that issues with third-party payers, including discounted managed care reimbursements and restrictive pharmacy benefit manager formulary control, caused Otezla sales to slow. *See* Ex. 47 (10/26/17 Call Tr.) at 2–5.

On October 26, 2017, Celgene announced that Otezla's sales during the third quarter totaled $308 million, a 12% year-over-year increase but a 14% decrease from the prior quarter. *See* Ex. 48 (10/26/17 8-K) at 2. That same day, Celgene reduced its 2017 guidance for Otezla sales to $1.25 billion. *See id.* at 4. Celgene also reduced its 2020 guidance for total product sales to $19–$20 billion from $21 billion. *See id.* Following the announcement of the guidance reductions for 2017 and 2020, Celgene's stock price dropped $19.57 per share, from $119.56 to $99.99. Compl. ¶ 269.

B. Argument

Plaintiff contends that Defendants misrepresented throughout the Class Period that Celgene was expected to meet its "2017 financial guidance" for Otezla sales. Compl. ¶ 342. According to Plaintiff, this guidance was unachievable from the moment it was first provided in 2014. *See id.* ¶¶ 209, 234.

1. Most of Defendants' Statements About Otezla Are Protected by the PSLRA's Safe Harbor for Forward-Looking Statements.

a. Plaintiff Largely Targets Forward-Looking Statements.

"Statements about future profitability and assumptions underlying management's expectations about the future fall squarely within the definition of a forward looking statement." *Aetna*, 617 F.3d at 281; *see also* § 78u-5(i). This includes statements about how or why one "expects" or "projects" particular results, or that one is "on track" to reach a projection. *See, e.g.*, *Avaya*, 564 F.3d at 255; *Waterford Twp. Police & Fire Ret. Sys. v. Mattel, Inc.*, 321 F. Supp. 3d 1133, 1150–51 (C.D. Cal. 2018); *Int'l Assoc. of Heat & Frost Insulators & Asbestos Workers Local #6 Pension Fund v. IBM*, 205 F. Supp. 3d 527, 537 (S.D.N.Y. 2016).

Almost all of the alleged misstatements about Otezla accordingly qualify as forward-looking statements, and they were identified as such when made. For example, Celgene's January 12, 2015 press release announced that "2017 net product sales [are] *expected* to be . . . $1,500 million to $2,000 million" for Otezla. Compl. ¶¶ 207, 381 (emphasis added). The press release also expressly stated that it "contain[ed] forward-looking statements, which . . . can be identified by the words 'expects,' . . . and similar expressions." Ex. 21 (1/12/15 8-K) at 4. Most of the other alleged misstatements about Otezla followed a similar pattern.[19]

[19] *Compare, e.g.,* Compl. ¶¶ 207, 382 (1/12/15 Pres'n); 384 (1/29/15 8-K); 232, 386 (3/4/15 Pres'n); 232, 387 (5/12/15 Pres'n); 232, 388 (6/10/15 Pres'n); 232, 389

b. Defendants' Forward-Looking Statements Were Accompanied by Meaningful Cautionary Language.

The statements made in January 2015 directed investors to consult the risks disclosed in Celgene's February 2014 10-K; the subsequent statements directed investors to consult the Safe Harbor Warnings contained in Celgene's subsequent 10-K filings. *See supra* n.19. As noted earlier, "[c]autionary statements disclosed in SEC filings may be incorporated by reference." *Aetna*, 617 F.3d at 282.

Celgene's cautionary language was the type of "extensive and specific" language the Third Circuit has found to be sufficiently meaningful as a matter of law. *Avaya*, 564 F.3d at 256–58. Indeed, Celgene's cautionary language identified the very risks that Plaintiff alleges caused Celgene to miss the 2017 Otezla sales guidance.

Plaintiff attributes Celgene's failure to meet the guidance "to three main issues: (i) Otezla's inferior efficacy compared to its competitors . . . ; (ii) challenges with insurance coverage for Otezla . . . ; and (iii) various other obstacles that made it

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(9/17/15 Pres'n); 232, 390 (11/10/15 Pres'n); 392–93 (4/28/16 Conf. Call); 395 (5/11/16 Pres'n); 398 (10/27/16 Conf. Call); 244, 400 (1/9/17 8-K); 401–02 (1/26/17 8-K and Conf. Call); 253, 405, 407–08 (4/27/17 8-K and Conf. Call); 412 – 13 (7/27/17 8-K and Conf. Call); 197–98 (9/17 Pres'ns); *with* Ex. 63 (1/12/15 Pres'n) at 2; Ex. 49 (1/12/15 Conf. Tr.) at 2; 381 (Jan. 12, 2015 Form 8-K); Ex. 21 (1/12/15 8-K) at 4; Ex. 29 (1/29/15 8-K) at 9; Ex. 30 (3/4/15 Pres'n) at 2; Ex. 31 (5/12/15 Pres'n) at 2; Ex. 32 (6/10/15 Pres'n) at 2; Ex. 33 (9/17/15 Pres'n) at 2; Ex. 34 (11/10/15 Pres'n) at 2; Ex. 35 (4/28/16 Pres'n) at 3; Ex. 36 (5/11/16 Conf. Tr.) at 1; Ex. 37 (10/27/16 Pres'n) at 3; Ex. 50 (1/9/17 8-K) at 5; Ex. 41 (1/26/17 8-K) at 8; Ex. 51 (1/26/17 Pres'n) at 3; Ex. 43 (4/27/17 8-K) at 7; Ex. 44 (4/27/17 Call. Tr.) at 2; Ex. 52 (7/27/17 8-K) at 8; Ex. 53 (7/27/17 Pres'n) at 3; Ex. 46 (7/27/17 Call Tr.) at 2; Ex. 54 (9/14/17 Pres'n) at 2; Ex. 55 (9/26/17 Pres'n) at 2.

difficult for patients to get Otezla or negatively impacted the ability of sales representatives to sell Otezla." Compl. ¶ 220; *see also id.* ¶¶ 209–19, 221–30, 248–50, 259–61. But Celgene warned that its projections were subject to exactly these risks, stating that Otezla's success "depends on acceptance by regulators, key opinion leaders, physicians, and patients as effective drugs with certain advantages over other therapies," which could be affected by Otezla's "efficacy, safety, price and benefits over competing products, as well as the reimbursement policies of third-party payers, such as government and private insurance plans." Ex. 23 (2/20/15 10-K) at 17; *see also* Ex. 22 (2/13/14 10-K) at 18. Celgene also warned that Otezla's sales could be affected by an "increased difficulty in obtaining and maintaining satisfactory drug reimbursement rates" and the possibility that "governmental and private third-party payers and purchasers [would] restrict access to formularies or otherwise discourage [the drug's] use." Ex. 22 (2/13/14 10-K) at 18; *see also* Ex. 23 (2/20/15 10-K) at 17, 19.

Celgene's cautionary language is like cautionary language that other courts, including the Third Circuit, have found to be meaningful. *See, e.g.*, *Avaya*, 564 F.3d at 257–58 (affirming dismissal); *Bauer v. Eagle Pharm., Inc.*, No. 16-cv-3091, 2017 WL 2213147, at *11 (D.N.J. May 19, 2017) (granting motion to dismiss); *Sanofi*, 87 F. Supp. 3d at 536 (granting motion to dismiss). The PSLRA safe harbor thus

immunizes all of Defendants' forward-looking statements about Otezla.[20]

c. Defendants' Forward-Looking Statements Were Not Made With Actual Knowledge of Their Falsity.

Alternatively, even if Celgene's cautionary language were not adequate, Plaintiff has not alleged that Defendants made their forward-looking statements about Otezla sales with "actual knowledge of [the statement's] falsehood," as the PSLRA requires. *Williams*, 869 F.3d at 245; *see* §§ 78u-4(b)(2)(A), 78u-5(c)(1)(B).

(i) Plaintiff's Claim Cannot Be Squared with Otezla's Track Record.

Plaintiff's theory is that—notwithstanding Otezla's strong performance in 2015 and 2016—Defendants engaged in a years-long fraud beginning in 2014 to knowingly mislead investors about what the drug's sales would be in 2017. But the Third Circuit has made clear that Otezla's track record all but precludes a finding that Defendants had actual knowledge that their statements were false.

Specifically, in *Avaya*, the plaintiff—like Plaintiff here—alleged that the defendants misleadingly expressed confidence in financial projections that the defendants allegedly "knew . . . could not be achieved" and, indeed, later missed. 564

[20] Plaintiff also claims that Defendants had a duty to "disclose all material facts" about the 2017 guidance and Otezla's sales after "putting these subjects into play." Compl. ¶ 396. But the safe harbor for forward-looking statements bars "any private action . . . that is based on an untrue statement of a material fact *or omission* of a material fact." § 78u-5(c)(1) (emphasis added); *see also, e.g.*, *Harris v. Ivax Corp.*, 182 F.3d 799, 806 (11th Cir. 1999); *Hoey*, 2018 WL 902266, at *19 n.16. There also is no duty to update a forward-looking statement. *See Advanta*, 180 F.3d at 536 (citing § 78u-5(d)).

F.3d at 249. The Third Circuit held, however, that the missed projections "more likely . . . were the product of recklessness or other nonculpable ignorance, rather than [the] knowing deception" required with forward-looking statements, because of the company's previous results. *Id.* at 274. The *Avaya* court emphasized that the company had hit its first quarter projections, and that the year went awry only afterwards, which "fatally weaken[ed] any inference of scienter" for statements made at the start of the second quarter or earlier. *Id.* at 275. In such circumstances, "the most compelling inference would be that [the defendants] . . . believed that [the second quarter] had picked up where the first quarter had left off." *Id.*

Avaya is directly on point. Contrary to Plaintiff's assertions that, by 2015, there were "numerous barriers that were impeding Otezla's net product sales and market share growth," Compl. ¶ 231, or that, as early as 2014, Otezla was "set[] up for consistently depressed sales going forward," *id.* ¶ 214, Otezla sales grew every quarter from the start of 2015 to the end of 2016—and then hit a record high in the second quarter of 2017. This run of success "fatally weaken[s] any inference" that Defendants were simultaneously engaged in "knowing deception" with respect to the 2017 projection. *Id.* at 274–75; *cf. Williams*, 869 F.3d at 245 ("[P]laintiffs' claim that the projections were impossible to achieve is undermined by the fact that the company ultimately substantially achieved the challenged projections.").

(ii) Plaintiff's Confidential Witnesses Do Not Demonstrate Actual Knowledge of Falsity.

Ignoring Otezla's robust sales history, Plaintiff largely relies on a scattershot of confidential witnesses who allegedly had doubts about Celgene's ability to hit the 2017 Otezla sales guidance. These witnesses' accounts should carry little if any weight.

For example, Plaintiff alleges that seven domestic sales representatives and regional sales managers each remember observing lackluster sales growth with Otezla. *See* Compl. ¶¶ 218 (FEs 8, 9, 10, 11, 12, 13), 219 (FE 14). But none of these individuals claims to have had access to Otezla's national or global sales data. *See, e.g.*, *Chubb*, 394 F.3d at 148 (affirming dismissal where "Plaintiffs rely heavily on former employees who worked in Chubb's local branch offices for information concerning Chubb's business on a national scale"). Moreover, one of these individuals (FE 13) left Celgene at the beginning of the Class Period and has no alleged basis of knowledge for sales at the company afterwards. Compl. ¶ 89. And of the remaining six, five (FEs 8, 10, 11, 12, 14) worked in the same part of the United States, giving further reason to doubt their ability to speak to Otezla's nationwide sales—much less Defendants' knowledge of the supposed lackluster sales in their regions, which none of them addresses. *See, e.g.*, *Chubb*, 394 F.3d at 153 ("It is far from clear how a branch manager would have knowledge of what Chubb executives knew."); *id.* at 156 ("[A]necdotal examples of profitable customers lost or policies renewed at flat or

slightly raised rates does not demonstrate that the rate initiative was failing.").[21]

Similarly, Plaintiff claims that two individuals observed weak sales internationally. *See, e.g.*, Compl. ¶ 225. But one (FE 15) left Celgene in 2015 and thus cannot speak to most of the Class Period. *Id.* ¶ 91. The other (FE 16) worked only in the United Kingdom, with no alleged basis of knowledge of sales elsewhere. *Id.* ¶¶ 92, 228–30. And neither, again, offers any purported insight into Defendants' state of mind. *See, e.g.*, *Chubb*, 394 F.3d at 148, 153, 155–56.

According to Plaintiff, beginning in late 2016, two other anonymous witnesses (FE 17 and FE 18) expressed concerns internally about Celgene's ability to meet the original 2017 guidance of $1.5–$2 billion in Otezla sales. *See* Compl. ¶¶ 236–37, 239, 507. But Plaintiff does not allege what these FEs said beyond just their opinion that the guidance "could not be met." Compl. ¶¶ 236–37, 244, 507.[22] Such "[o]missions and ambiguities count against inferring scienter," *Avaya*, 564 F.3d at 268 (quotation marks omitted)—particularly when Celgene *did* adjust the Otezla sales guidance in

[21] FE 9 similarly worked only in just one region. Compl. ¶ 218. Moreover, there is reason to doubt that these individuals' local perspectives typified Otezla's broader performance. For example, FE 8 and FE 9 both purportedly saw "flat" sales in 2015 and 2016, even though total Otezla sales increased 116% from 2015 to 2016. *See id.*

[22] FE 17 also allegedly claims "the Forecasting Team . . . was 'told to change' the numbers (i.e., the internal forecasts) by Smith and Curran to conceal the lack of growth." Compl. ¶ 238. But Plaintiff does not allege when this happened, whether any forecasts were changed, which forecasts were at issue, or how they were used. Nor are these internal forecasts even alleged to have been publicly disclosed.

January 2017.[23] And, in any event, FE 17's and FE 18's views are not alleged to have reached any of the individual Defendants other than Smith and Curran.

Plaintiff also relies heavily on an anonymous former employee (FE 7) who thought Celgene's sales strategy hobbled the drug's chances of meeting the original 2017 guidance. But FE 7's purported views show that he or she was no soothsayer. FE 7 allegedly doubted Celgene's strategy of obtaining market penetration through discounts (Compl. ¶¶ 211–12), but Plaintiff itself alleges that this strategy ultimately succeeded in "2017, when several large PBMs finally agreed to cover Otezla as an initial PA and psoriasis treatment." *Id.* ¶¶ 223, 258. And FE 7's view that Otezla was worse than its competitors, *id.* ¶ 216, is belied by Plaintiff's allegation that Otezla lacked its competitors' "well-known drawbacks, *id.* ¶ 106, as well as by Otezla's market share, which more than doubled to 23.3% between January 2015 and January 2017. *See* Ex. 56 (4/27/17 Call Pres'n) at 27. Moreover, even if FE 7's views had merit, they are not alleged to have reached any of the individual Defendants other than Smith, Curran, and Alles.

Finally, even if one accepts the confidential witnesses' purported views, the natural and most compelling inference is that others at Celgene simply disagreed with

[23] According to FE 18, a Celgene executive was purportedly fired in November 2017 for her "pushback" on the Otezla guidance, in order to "pivot around her." Compl. ¶ 243. But Celgene had already further reduced the 2017 Otezla guidance by then ("revealing" the purported years-long fraud). *Id.* ¶¶ 243, 524. Her exit thus hardly suggests that Defendants had been knowingly lying to investors for years.

them—not that Defendants agreed with these views but then knowingly lied to investors with a rosier picture, as Plaintiff's claim requires. *See, e.g.*, *In re Pretium Res. Inc. Sec. Litig.*, 256 F. Supp. 3d 459, 481 (S.D.N.Y. 2017) ("[D]ifferences of opinion, even stark differences . . . do not reveal scienter.").

2. Defendants' Other Statements About Otezla Are Not Actionable.

Plaintiff also alleges a handful of misstatements about Otezla that are not forward-looking in nature. But these statements are also not actionable.

First, the statements are largely nonactionable puffery. *See* Compl. ¶ 231, 233, 242, 395, 397, 398. The statement that Celgene "understand[s] the access environment very well" and has "great advantaged positions now because of the profile of [Otezla]," Compl. ¶ 395, is also "too vague to ascertain anything on which a reasonable investor might rely." *Aetna*, 617 F.3d at 284; *see also In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1428 (3d Cir. 1997) (statement "that the company 'believed [it could] continue to grow net earnings at a faster rate than sales'" was too vague to be actionable). And the statements are also all opinions that are actionable only if both not honestly held and without reasonable basis—and Plaintiff adequately alleges neither. *See supra* Part II.B.1.c.

Finally, Plaintiff also targets statements from an April 27, 2017 press release and accompanying call concerning Otezla's market size and sales trends. *See* Compl. ¶¶ 405, 406, 409. But Plaintiff alleges nothing about Otezla's market size in 2017 and

thus alleges no basis for a statement on that topic to be misleading. *See id.* As for statements about "increased gross-to-net adjustments," changed "managed care dynamics," and the like, Plaintiff *itself* alleges these as the reasons Celgene missed the 2017 guidance for Otezla sales. *See* Compl. ¶ 258–60.[24]

3. Plaintiff Does Not Allege Facts Giving Rise to a Strong Inference of Scienter.

Separately, Plaintiff has not alleged a strong inference of scienter for any of the statements about Otezla.[25] The stronger inference is that Defendants honestly and reasonably (or, at worst, negligently) maintained confidence in Otezla's sales projections, given the drug's history of strong performance.

This is particularly so when Plaintiff alleges no compelling reason why Defendants would lie to investors about Otezla. The stock sales by Alles, Curran, and Hugin do not suggest impropriety for the reasons discussed above. *See supra* Part II.B.3.c. Similarly, as discussed above, Plaintiff cannot establish scienter through any

[24] Nor can Plaintiff get any traction with an argument that Defendants were obligated to disclose more facts about Otezla. Disclosure is required "only when *necessary* 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'" *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011) (emphasis added) (ellipsis in original) (quoting 17 C.F.R. § 2401.10b-5(b)). Thus, there is no § 10(b) liability "for statements that are simply incomplete," because "revealing one fact about a product" does not require "reveal[ing] all others that, too, would be interesting, market-wise." *Winer Family Trust*, 503 F.3d at 330; *see also, e.g.*, *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002).

[25] As previously discussed, most of these statements were forward-looking and can be actionable only if made with actual knowledge of their falsity. Plaintiff has not met this burden for the reasons discussed above. *See supra* Part III.B.1.c.

executive departures, confidential witnesses, or the claim that Otezla fell within Celgene's "core operations." *See supra* Part II.B.2.a.iii, II.B.3.b., II.B.3.d.

IV. PLAINTIFF'S SECTION 10(B) CLAIM REGARDING OZANIMOD SHOULD BE DISMISSED.

A. Factual Background

1. Celgene Acquires Ozanimod During Ongoing Phase III Trials for the Drug.

Celgene acquired the rights to Ozanimod in July 2015, when it acquired Receptos, Inc. ("Receptos") for $7.2 billion. *See* Compl. ¶¶ 46, 65. Ozanimod was being developed by Receptos as a drug for the treatment of ulcerative colitis and relapsing multiple sclerosis ("RMS"). *Id.* ¶¶ 46, 271. At the time of the acquisition, Receptos had already conducted Phase I and Phase II clinical trials for Ozanimod as an RMS treatment, and Receptos also had already begun two Phase III trials for RMS, called RADIANCE and SUNBEAM. *Id.* ¶¶ 46, 281.

2. Celgene Conducts a Phase I Study Not Previously Done By Receptos.

In 2016, while the Phase III trials were ongoing, Celgene initiated several studies for Ozanimod that Receptos had not previously performed. One of these studies was a Phase I study (the "Mass Balance Study") that sought to "determine how [Ozanimod] moves through the body and how fast it is removed from the body." Compl. ¶ 297; *see also* Ex. 57 (5/4/18 Call Tr.) at 6; Compl. ¶¶ 293–94.[26] In late 2016,

[26] Phases of clinical trials need not follow a set sequence and can overlap. *See* 21 C.F.R. § 321.

the Mass Balance Study identified a metabolite (essentially a byproduct of the body breaking down the drug) that Celgene later called "CC-112273." Compl. ¶¶ 49, 297.

The presence of a metabolite can sometimes signal a safety concern. With Ozanimod, however, based on the "totality of the clinical data"—with nearly 4,000 patients having safely ingested Ozanimod during clinical trials—Celgene decided to proceed with its plan to file an NDA for Ozanimod in late 2017. Ex. 57 (5/4/18 Call Tr.) at 6. Thus, on January 9, 2017, Celgene stated during a J.P. Morgan Healthcare Conference that, "contingent on [the results of the Phase III trials, it] will file an NDA for Ozanimod in multiple sclerosis by the end of [2017]." Compl. ¶ 417.

3. Celgene Announces Positive Results from the Phase III Trials.

On February 17, 2017, Celgene issued a press release announcing positive results from one of the two Phase III Ozanimod trials for RMS (SUNBEAM). In top-line data from the trial, Ozanimod "demonstrated statistically significant and clinically meaningful improvements." Ex. 58 (2/17/17 8-K) at 1.

Celgene subsequently reaffirmed its intention to file an NDA for Ozanimod for RMS by the end of 2017. *See* Compl. ¶¶ 417–18, 420–23, 426, 429–33, 436, 440–42, 444–45, 447–53, 455–57, 461, 463, 465. And when it did so, Celgene directed investors to the warnings in its SEC filings, *see, e.g.*, Ex. 51 (1/26/17 Pres'n) at 2, which provided that:

> Forward-looking statements are subject to change and may be affected by risks and uncertainties, most of which are difficult to predict and are

> generally beyond our control. Forward-looking statements speak only as of the date they are made, and we undertake no obligation to update any forward-looking statement in light of new information or future events, although we intend to continue to meet our ongoing disclosure obligations under the U.S. securities laws and other applicable laws.
>
> * * * *
>
> We caution you that a number of important factors could cause actual results or outcomes to differ materially from those expressed in, or implied by, the forward-looking statements, and therefore you should not place too much reliance on them.

Ex. 23 (2/20/15 10-K) at 16; *see also* Ex. 17 (2/11/16 10-K) at 17. As part of the "important factors" referenced above, Celgene explained that "[t]he testing, manufacturing and marketing of our products require regulatory approvals, including approval from the FDA." *Id.*; *see also* Ex. 17 (2/11/16 10-K) at 18. Celgene also noted that the "principal risks to obtaining and maintaining regulatory approvals" include "[d]elays or rejections [that] may be encountered during any stage of the regulatory process if the clinical or other data fails to demonstrate compliance with a regulatory agency's requirements for safety, efficacy and quality." *Id.* at 18; *see also* Ex. 17 (2/11/16 10-K) at 18.

On May 22, 2017, Celgene issued a press release announcing positive results from Ozanimod's second Phase III trial for RMS (RADIANCE). *See* Ex. 59 (5/22/17 8-K) at 1. The press release reiterated Celgene's plan to file an NDA for Ozanimod by the end of the year. *See id.*

4. Consistent with Its Representations, Celgene Files the Ozanimod NDA by the End of 2017.

In December 2017, as it had represented it intended to do, Celgene filed its

NDA for Ozanimod for the treatment of RMS. Compl. ¶¶ 55, 319. Celgene publicly announced the filing on January 25, 2018. *Id.* ¶ 322.

5. The FDA Issues a Refusal-to-File Letter.

In a February 27, 2018 press release, Celgene announced that the FDA had issued an RTF letter in response to the Ozanimod NDA. An RTF is an initial rejection of an NDA that does not address the application's merits and instead allows for resubmission after the deficiencies are cured. *See* 21 C.F.R. § 314.101.[27] As Celgene's press release explained, "[u]pon its preliminary review, the FDA determined that the nonclinical and clinical pharmacology sections in the NDA were insufficient to permit a complete review." Compl. ¶ 489. The press release further stated that Celgene intended "to seek immediate guidance . . . to ascertain what additional information will be required to resubmit the NDA," and that Celgene would "work with the FDA to expeditiously address all outstanding items and bring this important medicine to patients." Ex. 61 (2/27/18 8-K) at 1. Following the press release, Celgene's stock fell $8.66 per share, from $95.78 to $87.12. Compl. ¶ 490.

On April 25, 2018, the investigators for the Phase III Ozanimod trials for RMS publicly presented data that explained how the CC-112273 metabolite is seen in

[27] Plaintiff is wrong to suggest that RTFs are "virtually unheard of" with large pharmaceutical companies. Compl. ¶¶ 56, 326. At least nine large pharmaceutical companies like Celgene have received RTFs since 2001, including Allergan, Abbvie, Gilead Sciences, Johnson & Johnson, Merck, Novartis, Pfizer, Roche, and Sanofi. *See* Ex. 60 (Herper Art.).

humans but not animals, suggesting that it might require additional testing. Compl. ¶ 495. Four days later, Morgan Stanley issued a report stating that "analysis of prior ozanimod pre-clinical studies suggest [that] CC112273 concentrations in prior pre-clinical work is unlikely to approximate human clinical doses," and "[t]herefore we believe it is increasingly likely mgt. will need to complete new preclinical work on CC112273 setting up a 1 to 3 year delay." Compl. ¶ 499. The following day, Celgene's stock fell $4.08 per share, from $91.18 to $87.10. *Id.* ¶ 501.

B. Argument

Plaintiff complains about Defendants' statements that (i) Celgene intended to file an NDA for Ozanimod by the end of 2017, when Phase III trials were completed, *see* Compl. ¶¶ 307, 417–18, 420–23, 426, 429, 431–33, 436, 440–42, 444–45, 447, 449–53, 455; (ii) the Phase III trials were ongoing, *see id.* ¶ 439; and (iii) Celgene filed the Ozanimod NDA in December 2017, *see id.* ¶¶ 461, 463, 465. Even though these statements were literally true—Celgene did in fact file the Ozanimod NDA by the end of 2017, and the Phase III trials were in fact ongoing when Defendants said they were—Plaintiff claims the statements were nonetheless misleading because Defendants failed to disclose that Celgene had yet to complete testing on the CC-112273 metabolite allegedly required by the FDA before it would approve the NDA. *Id.* ¶¶ 334, 435.

1. Plaintiff Fails to Identify a False or Misleading Statement About Ozanimod.

Plaintiff alleges no basis for finding Defendants' true statements about Ozanimod to have been misleading. Indeed, Plaintiff cites no authority for the purported "requirement" that metabolite testing had to be done before the filing of the Ozanimod NDA, and Plaintiff's other allegations indicate that metabolite testing is not mandatory. *See, e.g.*, Compl. ¶ 286 (quoting FDA as stating only that delayed metabolite testing can "cause development and marketing delays"); *id.* ¶ 289 (alleging that "the drugmaker *should* conduct additional testing of the metabolite before filing the NDA for the drug" (emphasis added)). Indeed, although the FDA guidance does include "recommended studies for assessing the safety of metabolites," the guidance describes itself as "nonbinding" and states that its "recommended" practices are "*not required*." Ex. 62 (11/16 Guidance) (emphasis added). Plaintiff's failure to allege facts demonstrating that Defendants' true statements about Ozanimod were nonetheless misleading requires the dismissal of Plaintiff's Section 10(b) claim regarding Ozanimod. *See, e.g.*, *City of Edinburgh*, 754 F.3d at 168, 172, 174 (affirming dismissal of claim that defendant's decision to start Phase III trials misrepresented strength of Phase II data, because the defendant never "made [a] statement about the strength of the" Phase II data and never stated that the start of its Phase III trial was contingent on certain Phase II results); *Hoey*, 2018 WL 902266, at *11.[28]

[28] Likewise, there is no basis for Plaintiff's claim that Defendant Tran's article in the *Journal of Clinical Pharmacology in Drug Development* was misleading. Compl. ¶¶ 310, 446.

2. Most of Defendants' Statements About Ozanimod Are Nonactionable Forward-Looking Statements.

Defendants' statements about Celgene's intention to file the Ozanimod NDA by the end of 2017 are also protected by the PSLRA's safe harbor for forward-looking statements. *See* Compl. ¶¶ 307, 308, 315, 417–18, 420–23, 425, 426, 429, 430–33, 436, 440–42, 443–44, 445, 447, 449–51, 452, 453, 455, 456. As noted earlier, "statements about FDA approval are classically forward-looking." *Sanofi*, 87 F. Supp. 3d at 535; *see also* 15 U.S.C. § 78u-5(i)(1)(B); *Hoey*, 2018 WL 902266, at *19.

Defendants' statements were identified as forward-looking and accompanied by meaningful cautionary language. The statements directed investors to consult Celgene's SEC filings for the relevant risk factors. And, as noted, Celgene's 10-K reports specifically warned, among other things, that "[d]elays or rejections may be encountered during any stage of the regulatory process if the clinical or other data fails to demonstrate compliance with a regulatory agency's requirements for safety, efficacy and quality." Ex. 23 (2/20/15 10-K) at 18; *see also* Ex. 17 (2/11/16 10-K) at 18. This cautionary language identified the very risk that later materialized and is similar to language that has required dismissal in other cases as well. *See, e.g.*, *Bauer*, 2017 WL 2213147, at *11; *Sanofi*, 87 F. Supp. 3d at 536.

Moreover, regardless of any cautionary language, Defendants' forward-looking

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Plaintiff complains that this article included three metabolites that were discovered in animal testing but did not mention CC-112273—but Plaintiff itself admits that CC-112273 was not significant in animals. *Id.* ¶ 301.

statements about filing the Ozanimod NDA are protected under the second prong of the safe harbor, because Plaintiff does not allege that these statements were made with "actual knowledge" of their purported falsity. *Williams*, 869 F.3d at 245. Again, Celgene did in fact file the Ozanimod NDA by the end of 2017. And there is no allegation that the Defendants who stated that Celgene intended to file an NDA by the end of 2017 (or made similar statements) knew that the FDA would reject the NDA if it did not include the results from the allegedly required metabolite testing.

Plaintiff cannot establish actual knowledge through the anonymous allegation (from FE 22) that the FDA purportedly told Celgene during a November 2017 meeting that the Ozanimod NDA needed to include the results of metabolite testing. Compl. ¶ 317. Plaintiff does not allege who attended this purported FDA meeting, which itself undermines the allegation. *See, e.g.*, *Rahman*, 736 F.3d at 245; *Chubb*, 394 F.3d at 154; *PDI*, 2006 WL 3350461, at *5. FE 22 was not even in the room and only allegedly "later learned" what was discussed. Compl. ¶ 317. And there is no allegation of how or from whom FE 22 allegedly "later learned" about the supposed meeting. *Id.* Confidential witness allegations carry little weight on a motion to dismiss when the witness "does not explain the source of his knowledge." *Utesch*, 316 F. Supp. 3d at 904; *see also Martin*, 2017 WL 3974002, at *12.[29]

[29] In addition, based on FE 22's description, "it is not clear how he or she would possess information regarding Defendants' knowledge or intent." *Adolor*, 616 F. Supp. 2d at 574. FE 22 was a "contractor for Receptos" who worked on the Ozanimod

Nor is any Defendant alleged to have been aware of this purported meeting. Thus, even if there were a proper basis for FE 22's alleged knowledge, it could not be imputed to Defendants. *See, e.g.*, *Bio-Tech.*, 380 F. Supp. 2d at 596 ("Mere allegations of knowledge on the part of subordinates do not provide a sufficient basis for imputing knowledge to executives.").

3. Far From Suggesting a Strong Inference of Scienter, Plaintiff's Ozanimod Allegations Are Deeply Implausible.

According to Plaintiff, Defendants misled investors about Ozanimod because: (1) "Celgene was motivated to submit the NDA prematurely in order to begin marketing Ozanimod and gain market share before generic versions of [another drug] began to enter the market in 2019," and (2) "many of Celgene's high-ranking employees were entitled to receive bonuses upon mere submission of the NDA to the FDA." Compl. ¶¶ 320–21.

But the first alleged motive fails on its face. If, as Plaintiff alleges, Defendants knew the NDA would be *rejected*, how would filing the NDA prematurely accelerate Ozanimod's timeline for *approval*? Moreover, what would Defendants gain from misleading investors about the NDA if a quick rejection was inevitable, as Plaintiff alleges? Plaintiff's theory is not even "cogent," and certainly not "as compelling" as the far more natural inference that Defendants were acting in good faith (or, at worst,

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team for ulcerative colitis "between late 2017 and early 2018." Compl. ¶ 98. Yet Celgene's NDA was for RMS, not ulcerative colitis.

negligently). *See OFI Asset Mgmt.*, 834 F.3d at 498 n. 16 ("It is unclear why Cooper would risk litigation at a critical time by materially misrepresenting a fact, only to disclose the same fact mere weeks later."); *Hoey*, 2018 WL 902266, at *21.[30]

Nor is Plaintiff's second theory, about the purported bonuses, any better. Plaintiff alleges that two individuals (Jean-Louis Saillot and Defendant Martin) received bonuses merely for filing the Ozanimod NDA. *See* Compl. ¶¶ 321, 508. Yet only Martin allegedly made a statement about the Ozanimod NDA, when he stated in October 2017 that "we are working hard . . . to get ready to file by the end of the year." *See id.* ¶ 455. Even if the filing entitled Martin to a bonus, that would have been no reason for him to *mislead investors*—as his vanilla statement would have had no impact on the potential bonus.[31] And why would the other Defendants mislead the market because of a bonus due to Martin or Saillot? Plaintiff offers no reason.

Indeed, there is no plausible basis for any other Defendant to have misled investors about the NDA. As previously demonstrated, the anonymous allegation that the FDA informed Celgene about the need for metabolite testing deserves no weight. *See supra* Part IV.B.2. The stock sales of Alles, Curran, and Hugin also do not

[30] Relatedly, what would be the upside of accelerating the NDA when there were allegedly concerns "that an RTF would cause heads to roll locally and up top at Celgene"? Compl. ¶ 314 (internal quotation marks omitted).

[31] Moreover, Plaintiff alleges these bonus payments on the basis of two anonymous witnesses (FE 20 and FE 22). Compl. ¶ 321. Yet Plaintiff never alleges the source of either individual's purported knowledge, and there is ample reason to doubt their accounts. FE 20 left Receptos about a year before the Ozanimod NDA was filed. *Id.* ¶ 96. FE 22 was a Receptos contractor who was not on the RMS team. *Id.* ¶ 98.

give rise to a strong inference of scienter for the many reasons discussed above. *See supra* Part Part II.B.3.c. Nor do any employee departures from Celgene. *See* supra Part II.B.3.d. And no weight is due to the allegation that Alles, Hugin, Kellogg, and Smith *might* have received bonuses for the Ozanimod NDA filing. Compl. ¶ 321. Plaintiff never alleges that these individuals *actually* received such bonuses.

V. PLAINTIFF'S SECTION 20(A) CLAIM SHOULD BE DISMISSED.

Plaintiff's Section 20(a) claim should be dismissed as well. Plaintiff brings this claim only against Defendants Alles, Kellogg, Smith, Curran, Hugin, and Fouse (the "Section 20(a) Defendants"). *See* Compl. ¶ 548.

Section 20(a) "creates a cause of action against individuals who exercise control over a 'controlled person,' including a corporation, that has committed a violation of Section 10(b)." *Avaya*, 564 F.3d at 252; *see* 15 U.S.C. § 78t(a). Section 20(a) liability is thus "derivative of an underlying violation of Section 10(b)." *Avaya*, 564 F.3d at 252. Because Plaintiff has not alleged an underlying Section 10(b) violation, Plaintiff's Section 20(a) claims also should be dismissed. *See, e.g.*, *Aetna*, 617 F.3d at 285.

In addition, Section 20(a) liability requires the defendant to "have been a 'culpable participant' in the act or acts constituting the violation," which requires knowledge of the underlying violation. *Belmont v. MB Inv. Partners, Inc.*, 708 F.3d 470, 484, 486 (3d Cir. 2013) (quotation marks omitted). Even if Plaintiff has adequately alleged a Section 10(b) claim, Plaintiff has not adequately alleged that the Section 20(a) Defendants had actual knowledge of the fraud. *See supra* Parts II.B.2., III.B.1, IV.B.2.

For this reason, too, Plaintiff's Section 20(a) claim should be dismissed.

CONCLUSION

For the foregoing reasons, the Court should dismiss the Amended Complaint. And because, as a matter of law, Plaintiff cannot cure these deficiencies, the Court should dismiss the Amended Complaint with prejudice.

Dated: New York, New York
February 8, 2019

Respectfully submitted,

/s/ Lawrence S. Lustberg

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